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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,838	11/29/2001	Hans Hofland	P 23,643-A USA	6395

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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/996,838

Applicant(s)

HOFLAND ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: All claims would remain rejected for the reasons of record.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit: 1633

Continuation of 3. NOTE: Applicants have amended claim 1 to modify the process for making the stable colloids of the present invention. Applicant's modification of this process would result in further consideration and/or search for stable colloids potentially produced from the modified process recited in claim 1.

Moreover, Applicants have amended to claim 1, line 2 to recite "a complex which comprises DNA sequestered therein." Moreover, claim 1, line 5, also recites "a complex." Applicant's amendment would necessitate a new grounds of rejection under 35 USC 112, 2nd paragraph, since it is unclear if the complex recited in line 2 of claim 1 is the same complex recited in line 5 of this claim. Note that claim 1, line 5, does not recite "said complex" or "the complex." Therefore, the metes and bounds of Applicant's invention recited in claim 1, and those claims dependent therefrom are vague and indefinite since the process recited in claim 1 is vague and indefinite. Additionally, the rejection under 35 USC, 112, 1st paragraph, new matter, would remain, for the reasons of record.

On page 11 of the response filed 8-14-06, particularly in the last paragraph, Applicants stated that the examiner did not address their arguments regarding the rejection of claims 1, 7, 11, 14-15, 18 to 23, and 28-30 under 35 USC 103(a), particularly in regards to the "expectation of success" of the combination of references cited in this rejection. Contrary to Applicant's assertions, it was previously stated in the bridging paragraph of pages 14-15 of the Final Rejection mailed 3/09/05:

"One of ordinary skill in the art would also have been motivated to employ any known reagent, such as a buffer containing N-Hydroxysuccinimide esters or citraconic anhydride, which is conventionally employed in the prior art for charge modification, for charge modification of the surface of any amino lipid/DNA particles or cationic head group containing lipid/DNA particles. One of ordinary skill in the art would have been motivated to do so because both Semple teaches that a buffered solution can be used to neutralize the positive charges present on the surface of a lipid/DNA complex, and because Trubetskoy teaches that an addition of polyanionic molecules would enhance the transfer activity of a DNA/cationic lipid complex. One of ordinary skill in the art would have expected that N-Hydroxysuccinimide esters or citraconic anhydride are suitable reactive groups because Monahan teaches the use of the reagents in a charge modification of a cationic molecule such as a cationic amino group, and further teaches that gene expression is most efficient when the overall net charge of the complexes is negative. One would have a reasonable expectation of success of being able to efficiently deliver and express a DNA of choice in vivo as long as the overall net charge of the complexes as a result of a charge modification is neutral or negative."

Applicant's have not provided any evidence to overcome the prima facie case of previously made of record. As per MPEP § 2144.08 B, "[I]f a prima facie case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the prima facie case. See, e.g., *Dillon*, 919 F.2d at 692, 16 USPQ2d at 1901. Rebuttal evidence and arguments can be presented in the specification, *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995), by counsel, *In re Chu*, 66 F.3d 292, 299, 36 USPQ2d 1089, 1094-95 (Fed. Cir. 1995), or by way of an affidavit or declaration under 37 CFR 1.132, e.g., *Soni*, 54 F.3d at 750, 34 USPQ2d at 1687; *In re Piasecki*, 745 F.2d 1468, 1474, 223; USPQ 785, 789-90 (Fed. Cir. 1984). However, arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984)."

All other arguments appear to be directed to the claims as presented in the amendment of 8-14-06 are obviated since this amendment was not entered.



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